IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF UTAH, NORTHERN DIVISION

HEIDI MARION and MICHAEL MARION, husband and wife, Plaintiffs, v. SMITH & NEPHEW, INC., a Delaware Corporation, Defendant.	Case No. 1:15-cv-00096-JNP-BCW **MEMORANDUM DECISION & ORDER GRANTING DEFENDANT'S MOTION TO DISMISS FOR FAILURE TO STATE A CLAIM AND GRANTING PLAINTIFFS' REQUEST FOR LEAVE TO FILE AN AMENDED COMPLAINT** Judge Jill N. Parrish

Before the court is Defendant Smith & Nephew, Inc.'s, Motion to Dismiss on the Basis of Preemption and for Failure to State a Claim upon which Relief can be Granted. (Docket 12).

BACKGROUND

This case presents products liability claims arising from Smith & Nephew's Birmingham Hip Resurfacing (BHR) System, a medical device implanted in a person's hip to treat damage to the hip joint. To market and sell the BHR device, the law required Smith & Nephew to obtain pre-market approval from the U.S. Food and Drug Administration (FDA). On May 9, 2006 Smith & Nephew received conditional approval to market and sell the device. On August 7, 2007, Plaintiff Heidi Marion underwent a resurfacing procedure to repair arthritic damage to her left hip during which Ms. Marion's physician implanted Smith & Nephew's BHR System. Six years later, Ms. Marion's BHR System failed and toxic levels of cobalt and chromium shed into her body. As a consequence, Ms. Marion underwent revision surgery on August 6, 2013. Both

Ms. Marion and her husband bring various claims for relief against Smith & Nephew relating to the BHR System's alleged premature failure.

ANALYSIS

Smith & Nephew moves to dismiss all claims against it on grounds that the Marions' claims are either preempted or fail to allege sufficient facts to state a claim on which relief may be granted. The Marions respond that their claims are not preempted and have been properly plead. Alternatively, the Marions request leave to amend their Complaint.

I. Legal Standard

To survive a Rule 12(b)(6) motion to dismiss, a plaintiff must "state a claim upon which relief can be granted." Fed. R. Civ. P. 12(b)(6). To do so, a plaintiff must plead both a viable legal theory and "enough factual matter, taken as true, to make [the] 'claim to relief . . . plausible on its face." *Bryson v. Gonzales*, 534 F.3d 1282, 1286 (10th Cir. 2008) (quoting *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 570 (2007)). In the context of medical devices that have received pre-market approval from the FDA, stating a legally viable state law claim "has been compared to the task of navigating between Scylla and Charybdis." *Caplinger v. Medtronic, Inc.*, 784 F.3d 1335, 1340 (10th Cir. 2015). "Exercising its authority under the Supremacy Clause," *id.* at 1336, Congress enacted a preemption provision as part of the Medical Device Amendments (MDA) to the Federal Food, Drug, and Cosmetics Act (FDCA):

> Except as provided in subsection (b) of this section, no State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement--
> **(1)** which is different from, or in addition to, any requirement applicable under this chapter to the device, and
> **(2)** which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.

21 U.S.C. § 360k(a). Although the language of this provision is "expansive" and could have been applied to preempt "all private state law tort suits," the Supreme Court has adopted a nuanced interpretation of § 360k(a) that is both narrower and more complicated. *See Caplinger*, 784 F.3d at 1337

In *Medtronic, Inc. v. Lohr*, 518 U.S. 470 (1996), the Supreme Court held that "tort suits do not impose new 'requirements' on manufacturers and are not preempted so long as the duties they seek to impose 'parallel' duties found in the FDCA." *Caplinger*, 784 F.3d at 1338 (quoting *Lohr*, 518 U.S. at 495). "[S]tate and federal law duties 'parallel' each other not only when they are identical, but also when state law imposes duties on the defendant that are 'narrower, not broader' than those found in the FDCA." *Id.* (quoting *Lohr*, 518 U.S. at 495).

In addition, *Lohr* held that the text of § 360k(a) preempting state laws "to the extent they conflict with 'any [federal] requirement applicable under this chapter to the device'" meant that only regulations "'specific' to a 'particular device'" were "capable of preempting any different or additional state requirement." *Id.* at 1339 (quoting *Lohr*, 518 U.S. at 498-99). "Put differently, [to be preempted] a device must undergo the premarket approval process . . . [l]awsuits aimed at less highly regulated devices . . . are not preempted.'" *Id.*[1]

The Supreme Court next addressed preemption under the FDCA in *Buckman Co. v. Plaintiffs' Legal Committee*, 531 U.S. 341 (2001). In *Buckman*, the Supreme Court held that 21 U.S.C. § 337(a) "preempts any state tort claim that exists 'solely by virtue' of an FDCA

[1] While the Supreme Court left room for preemption to displace some state tort suits against lesser regulated products, it did not identify the basis for such preemption. *See Caplinger*, 784 F.3d at 1339 ("To be sure, *Lohr* itself wasn't unequivocal on this point: the Court acknowledged the possibility that 'general' federal requirements might sometimes preempt state requirements. But when it comes to when and what kinds of 'general' requirements have preemptive effect, or what sort of device-specific regulations beyond the premarket approval process might bear that same power, *Lohr* told us little." (citations omitted)).

violation." *Caplinger*, 784 F.3d at 1339 (quoting *Buckman*, 531 U.S. at 353). "At the same time, the Court left undisturbed the portion of *Lohr* allowing state lawsuits based on 'traditional state tort law' that 'predate[s]' the FDCA but happens to 'parallel' it." *Id.* Most recently, in *Riegal v. Medtronic, Inc.*, 552 U.S. 312 (2008), the Supreme Court held that "*any* state requirement, whether device specific or generally applicable, is preempted when it differs from or adds to federal requirements." *Caplinger*, 784 F.3d at 1339 (emphasis in original).

Thus, to state a legally viable claim that avoids preemption under the FDCA, a plaintiff must first plead either that "there exists [no] device-specific federal requirement[s]," or that "the state law duty is narrower than or equal to the federal duty." *See id.* at 1340. Second, a plaintiff must plead that the state law duty "predates the [federal statutory scheme]." *See id.* Ultimately, if a plaintiff's claims survive the preemption analysis, they must also be supported by sufficient factual allegations to make them "plausible on [their] face." *Bryson*, 534 F.3d at 1286 (quoting *Twombly*, 550 U.S. at 570).

II. The Marions' Allegations Against Smith & Nephew

The Marions brought twelve state law claims for relief. In pleading these claims, the Marions failed to satisfy the pleading standard outlined above. In responding to the Motion to Dismiss, both in the briefing and at oral argument, the Marions acknowledged "divergent views" and "'uncertainty' among the lower courts" with respect to the application of § 360k(a). *See Caplinger*, 784 F.3d at 1337. Given the disparate outcomes and uncertainty among the federal courts on this issue, the court understands the Marions' initial uncertainty with respect to the required pleading standard. While "the difficulty of crafting a complaint sufficient to satisfy all

[the] demands" of § 360k(a) is not a proper legal basis for allowing a plaintiff to proceed to discovery, the court does find it sufficient to warrant leave to amend.

The court therefore dismisses the Complaint for failure to state a claim upon which relief may be granted, but the court grants plaintiffs leave to file an amended complaint no later than January 15, 2016. In an effort to further clarify the required pleading standard for the amended complaint, the court outlines some examples of the specific deficiencies in the Marions' complaint, as well as the court's understanding of the requirements for pleading claims in light of § 360k(a).

First, the Marions' initial complaint fails to identify with specificity the federal law requirements that parallel the state law claims. In the entire complaint, the Marions only once cite federal law, and this citation is to the entire FDCA. (*See* Complaint ¶ 50.) This blanket allegation is insufficient to satisfy the requirement to plead the specific federal requirements that parallel state law. The courts are under no "obligation to perform [the] work [of] searching out theories and authorities [the plaintiff] has not presented." *Caplinger*, 784 F.3d 1342. It is the plaintiff's responsibility to search "the heap of federal law [for] parallel provisions [that might] exist . . . . After all, the FDA's medical device regulations alone cover 592 pages of eight-point type and the Supreme Court has suggested that in searching for a parallel federal duty a plaintiff may scour them all as well as the statute itself." *Id.*

If the Marions believe specific federal requirements for the BHR System are solely within the possession of Smith & Nephew, the amended complaint should state this and outline the allegations on information and belief to the best of the Plaintiffs' ability. In all other respects, the amended pleading of the federal requirements should be specific enough to permit the court

to evaluate whether the stated requirement in fact applies to the device at issue. Likewise, the court should be able to determine from the amended complaint whether the federal requirement parallels the corresponding state law duty.

Next, the Complaint fails to identify with specificity the state law duties that allegedly parallel the requirements for the BHR System under federal law. The initial complaint lacks the required specificity inasmuch as it contains only general references to state common law duties and the Utah Product Liability Act. (*See* Complaint ¶¶ 51, 59.) In the amended complaint, the Marions must set forth the parallel state law duties with sufficient clarity to enable the court to assess preemption. Specifically, the court must first be able to determine whether the state law duty pre-dates and exists independently of the identified parallel federal requirement.

In their opposition and at oral argument, the Marions asserted that a violation of a federal safety statute or regulation is evidence of negligence and that the common law doctrine of negligence would provide the basis for parallel state law claims. But this argument runs expressly counter to the Supreme Court's interpretation of § 337(a). *See Buckman*, 531 U.S. at 353 (holding that preemption applies when "the existence of . . . federal enactments is a critical element in [the] case"). The amended pleadings must identify state law duties that predate and operate independently from the federal law requirements. Likewise, the state law duties should be identified with sufficient clarity to allow the court to determine whether they are in fact narrower than or equal to the federal law requirements. This will require identifying the state law sources of the duties or requirements with greater specificity than a general citation to state common law or statute.

Finally, the Marions must be careful to articulate the specific factual allegations that plausibly establish entitlement to relief. To the extent certain facts are unavailable because they are in the exclusive possession of Smith & Nephew, it is appropriate to plead the facts that are known and allege on information and belief those allegations that are impossible to specifically assert without access to discovery.

CONCLUSION

The Marions have failed to properly plead their claims against Smith & Nephew. Accordingly, the Court GRANTS Smith & Nephew's Motion to Dismiss for failure to state a claim. The dismissal is without prejudice. The Marions are given leave to file an amended complaint no later than January 15, 2016.

Dated this 1st day of December, 2015.

BY THE COURT:

JILL N. PARRISH, Judge
United States District Court